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PARtorney's Docket No. <u>PA-5335-RFB</u>

PATENT

FEB 1 2 2007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

application of: Bates et al.

Customer No.: 9896

Serial No: 10/618,977

Group No.: 3738

Filed: July 14, 2003

Examiner: Thomas Sweet

For:

COATED MEDICAL DEVICE

Commissioner for Patents Alexandria, VA 22313

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT BEFORE MAILING DATE OF EITHER A FINAL ACTION OR NOTICE OF ALLOWANCE (37 CFR 1.97(c))

NOTE: "An information disclosure statement shall be considered by the Office if filed ... before the mailing date of either (1) a

final action under § 1.113 or (2) a notice of allowance under § 1.311, whichever occurs first, provided the statement is accompanied by either a certification as specified in paragraph (e) of this section or the fee set forth in § 1.17(p)." 37

CFR 1.97(c).

NOTE: "If a final action or notice of allowance is mailed in an application and later withdrawn, the application will be considered as not having had a final action or notice of allowance mailed for purposes of considering an information disclosure

statement." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

CERTIFICATE OF MAILING/TRANSMISSION (37 CFR 1.8a)

I hereby certify that this correspondence is, on the date shown below, being:

MAILING

[x] deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner of Patents and Trademarks, P.O. Box 1450, Alexandria, VA 22313-1450 FACSIMILE

[] transmitted by facsimile to the Patent and Trademark Office

Signature

Pamm Garwood

(Type or print name of person certifying)

(Transmittal of Information Disclosure Statement before Mailing Date of Either A Final Action Or Notice of Allowance [6-4] -- Page 1 of 3)

NOTE: "If information submitted during the period set forth in 37 CFR 1.97(c) with a certification is used in a new ground of rejection on unamended claims, the next Office action will not be made final since in this situation it is clear that applicant has submitted the information to the office promptly after it has become known and the information is being submitted prior to a final determination on patentability by the Office. However, the information submitted with a certification can be used in a new ground of rejection and the next Office action made final, [if] the new ground of rejection was necessitated by amendment of the application by applicant. Where the information is submitted during this period with a fee, the examiner may use the information submitted, e.g., printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. See MPEP 706.07(a). If a new ground of rejection is introduced that is neither necessitated by an amendment to the claims nor based on the information submitted with the fee set forth in 37 CFR 1.17(p), the Office action shall not be made final." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

WARNING:

"A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 CFR 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

TIME OF TRANSMITTAL OF ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

- 1. The information disclosure statement transmitted herewith is being filed after three months of the filing date of this national application or the date of entry of the national stage as set forth in § 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but before the mailing date of either:
 - (1) a final action under § 1.113 or
 - (2) a notice of allowance under § 1.311,

whichever occurs first.

CERTIFICATION OR FEE

2.	Accompanying this transmittal is:	(check either A or B below,
	A. [] a certification as specifie	d in 37 CFR 1.97(e)

OR

B. [x] the fee set forth in 37 CFR 1.17(p) for submission of an information disclosure statement under § 1.97(c). (\$180.00).

FEE PAYMENT

(Complete this item, if applicable)

3. Applicant elects the option to pay the fee set forth in 37 CFR 1.17(p) for submission of an information disclosure statement under § 1.97(c). (\$180.00)

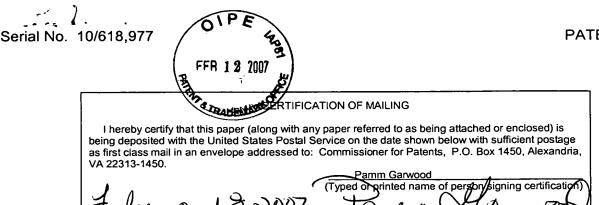
Fee due \$ _ 180.00	
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(Transmittal of Information Disclosure Statement before Mailing Date of Either A Final Action Or Notice of Allowance [6-4] -- Page 2 of 3)

METHOD OF PAYMENT OF FEE

4.	[] Attached is check in the amou	nt of \$
	[X] Charge Account No. 13-2528 A duplicate of this request is a	
	If any additional fees are due, plea	se charge Account No. 13-2528.
Da	ate: Feb 7, 2007	SIGNATURE OF ATTORNEY)
Re	eg. No.: 30,056	Richard J. Godlewski (Type or print name of attorney)
Te	el. No.: (812) 330-1824	P.O. Box 2269 (P.O. Address)
		Bloomington, IN 47402

Signature



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Case No. PA-5335-RFB

In re Application of:

Bates et al.

Date

Serial No: 10/618,977

Filed: July 14, 2003

For: COATED MEDICAL DEVICE

Examiner: Thomas Sweet

Group Art Unit: 1762

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with the duty of disclosure under 37 C.F.R. §1.56 and §§1.97 -1.98, and more particularly in accordance with 37 C.F.R. §1.97(d), Applicants are enclosing Form PTO-1449 (2 sheets), along with a copy of each listed reference for which a copy is required under 37 C.F.R. §1.98(a)(2).

The following references are being submitted in a foreign language without a translation:

Cite No. C20 DE4225553 discloses a balloon catheter with inner and outer balloons for cardiology, allowing application of both dilatation and active agents.

DE4446694A1 discloses the use of urea or prostaglandin Cite No. C21 especially prostacyclin to improve imaging in Xray, ultra sounds, nuclear and MRI diagnoses. The prostaglandin is preferably combined with use of contrast agent.

Cite No. C22 D69403966 discloses compositions comprising arran (வரும்) இது முறியாகள் இரையாகள் இது ம factor, and a polymeric carrier. Representative examples of anti-angiogenic factors

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Serial No. 10/618,977 PATENT

include Anti-Invasive Factor, Retinoic acids and derivatives thereof, and taxol. Also

provided are methods for embolizing blood vessels, and elminating biliary, urethral,

esophageal, and tracheal/bronchial obstructions (see WO95/03036A1).

Cite No. C23 DE10244847.7 discloses a drug delivering medicinal device, such

as a balloon catheter or stent, having surface coating of lipophilic, water-insoluble drug

to be released immediately on contact with tissue in specific diseased region.

Cite No. C33 WO97/26862 relates to additives for concentrated injection and

infusion solutions which prevent or reduce acute or delayed oversensitivity reactions

and injection and infusion solutions containing said additives.

Applicants respectfully request the Examiner's consideration of the above

references and entry thereof into the record of this application.

By submitting this Statement, Applicants are attempting to fully comply with the

duty of candor and good faith mandated by 37 C.F.R. §1.56. As such, this Statement is

not intended to constitute an admission that any of the enclosed references, or other

information referred to therein, constitutes "prior art" or is otherwise "material to

patentability", as that phase is defined in 37 C.F.R. §1.56(a).

Please address all correspondence to:

Richard J. Godlewski

Patent Attorney

P.O. Box 2269

Bloomington, IN 47402-2269

(812) 330-1824

Respectfully,

Date: 7 2007

ttorney for Applicant

Richard J. Gogliewski

Reg. No. 30,056

PTO/SB/08A (08-00)

Approved for use through 10/31/2002, OMB 0651-0031 Please type a plus sign (+) inside this box Please type a plus sign (+) inside this box → Under the Paperwork Reduction Act of 1995, no persons are required to U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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8	Substitute for form	1449/	VPTO	Application Number	10/618,977	
INFO	MATION D	iec	LOSUPE	Filing Date	July 14, 2003	
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT			First Named Inventor	Brian Bates, et al.	
SIAI				Group Art Unit	1762	
(us	e as many sheets	as ne	cessary)	Examiner Name	Thomas Sweet	
Sheet	1	of	2	Attorney Docket Number	PA-5335-RFB (8627/742)	

U.S. PATENT DOCUMENTS

		U.S. Patent Do	ocument		Date of Publication of	Pages, Columns, Lines, Where Relevant
Examiner Initials*	Cite No.	Number	Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear
	C1	5,051,257		Pietronigro	09/24/1991	
	C2	5,320,634		Vigil et al.	06/14/1994	
	СЗ	5,370,614		Amundson et al.	12/06/1994	
	C4	5,554,182		Dinh et al.	09/10/1996	
	C5	5,571,086		Kaplan et al.	11/05/1996	
	C6	5,626,562		Castro	05/06/1997	
, .	C7	5,792,158		Lary	08/11/1998	
	C8	6,039,721		Johnson et al.	03/21/2000	
	C9	6,146,358		Rowe	11/14/2000	
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	C13	6,544,544		Hunter et al.	04/08/2003	
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	C15	6,616,650	B1	Rowe	09/09/2003	
	C16	2002/0123505	A1	Mollison et al.	09/05/2002	
•	C17	2003/0100600	A1	Kinsella et al.	05/29/2003	
	C18	2005/0250672	A9	Speck et al.	11/10/2005	
	C19	2006/0020243	A1	Speck et al.	01/26/2006	

FOREIGN PATENT DOCUMENTS

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Examiner Initials*	Cite No.	For Office 3		nent d Code ⁵ nown)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶			
	C20	DE	4225553	C1	Michael Rudolf	05/11/1994			ı		

EXAMINER	DATE	
SIGNATURE	CONSIDERED	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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	F. Inc. B.	Complete if Known
Substitute for form 1449A/PTD FER	Application Number	10/618,977
INFORMATION DISCLOSINE	Filingspate	July 14, 2003
STATEMENT BY APPLICANT	Named Inventor	Brian Bates, et al.
STATEMENT BY APPLICANCE	Group Art Unit	1762
(use as many sheets as necessary)	Examiner Name	Thomas Sweet
Sheet 2 of 2	Attorney Docket Number	PA-5335-RFB (8627/742)

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		For	eign Patent Docume	ent		Date of Publication of	Pages, Columns, Lines, Where Relevant	
Examiner Initials*	Cite No.	Office ³	Kind (Number ⁴ (if kno	Code ⁵ wn)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear	T 6
	C21	DE	4446694		Schering AG	12/1994		
	C22	DE	69403966	<u> </u>	Burt et al.	02/05/1998		
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	C24	EP	0706376		Angiotech Pharm. Inc.	07/19/1993		
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1	C35	wo	98/43618		Neorxcorp.	03/1997		
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	C37	wo	0006152		Novopharm Biotech	07/1998		
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	C39	wo	00/44414	A1	You-Ling Fan	08/03/2000		
	C40	wo	00/45744		Dachuan Yang	08/10/2000		
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	C42	wo	03/026718	A1	Anthony Ragheb	04/03/2003		
	C43	wo	03/048166		Gaedicke e al.	06/12/2003		
	C44	wo	2004/028610	A2	Ulrich Speck et al.	04/08/2004		

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